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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,890	04/28/2000	ULRICH H. KOSZINOWSKI	203640	6925

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EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	PAPER NUMBER
1636	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

09/463,890

Applicant(s)

KOSZINOWSKI ET AL.

Examiner

Daniel M. Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36,37,40-70,73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36,37 and 40-70 is/are allowed.
- 6) ☒ Claim(s) 73 and 74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                                  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

This Office Action is a reply to the Paper filed 19 January 2007 in response to the Non-Final Office Action mailed 30 October 2006. Claims 36, 37, 40-70, 73 and 74 were considered in the 30 October Office Action. No claim amendments were presented in the 19 January Paper. Claims 36, 37, 40-70, 73 and 74 are pending and under consideration.

#### ***Response to Amendment and Arguments***

##### **Priority**

In the previous Office Action, benefit of the foreign priority document was denied because the German application was not enabling for a BAC containing any bacterial nucleic acid sequences. In the remarks filed with the 19 January Paper, Applicant points out that the German priority document and the instant application disclose construction of a BAC vector derived from an *E. coli* mini-F plasmid and contends that, given the teachings of the application and the knowledge available in the art, the priority application is fully enabling for what is now claimed.

This argument is deemed persuasive. According to the plain meaning of the limitation “bacterial artificial chromosome”, the instant claims are reasonably construed as limited to constructs capable of replicating and propagating large nucleic acid molecules in bacterial cells, such as those disclosed in the German application and known in the prior art. Given this interpretation of the claims, the claims are entitled to benefit of the foreign priority application.

Art Unit: 1636

Claim Rejections - 35 USC § 102 & 103

Rejection of claims 36, 37, 40-43, 46-48, 50-51, 53-54, 56-64 and 67-70 under 35 U.S.C. 102(a) as being anticipated by Messerle et al (PNAS USA, December 1997, Vol. 9, pages 14759-14763) is **withdrawn** in view of the perfection of the foreign priority filing.

Rejection of claims 36, 48, 51, 54, 57-60, 63-64 and 67-69 under 35 U.S.C. 102(e) as being anticipated by Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998 is **withdrawn** in view of the perfection of the foreign priority filing.

Rejection of claims 36, 43, 48, 51, 54, 57-60 and 63 under 35 U.S.C. 102(a) as being anticipated by Delecluse et al (Proceedings of the National Academy of Sciences, USA. 7 July 1998, Vol. 95, pages 8245-8250) is **withdrawn** in view of the perfection of the foreign priority filing.

Rejection of claims 37, 40-43 and 72 under 35 U.S.C. 103(a) as being unpatentable over Horsburgh et al (U.S. Patent No. 6,277,621 B1, filed on 2/26/1998; see the entire patent) in view of Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p.B8, 1996) is **withdrawn** in view of the perfection of the foreign priority filing.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1636

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 73-74 **stand rejected** under 35 U.S.C. 102(b) as being anticipated by Messerle et al (Journal of Molecular Medicine, Vol. 74, No. 4, p. B8, 1996) for the reasons set forth in the 30 October Office Action commencing at page 6.

*Response to Arguments*

In response to the *prima facie* rejection of record, Applicant contends that the reference does not apply because Messerle et al. teaches that transfection of each of the plasmids disclosed therein into eukaryotic cells did not result in the production of a progeny. Applicant concludes in view of this teaching that the plasmids described by Messerle do not contain an infectious herpes virus genomic sequence. Applicant further contends that the skilled artisan would not be able to obtain a homogeneous plasmid preparation by the method of Messerle. Applicant concludes that the teachings of Messerle do not anticipate the claims because the instant claims are directed to an infectious mutagenized herpes virus genomic sequence larger than 100 kb that is homogenous and produced from a single BAC vector.

This argument has been fully considered but is not deemed persuasive because it is based on an overly narrow interpretation of the claims. First, it is noted that the claims do not require that the infectious herpes virus genomic sequence be present as a homogeneous population. Furthermore, the claims do not require that the infectious herpes virus genomic sequence be in the form of a plasmid.

Art Unit: 1636

Applicant is reminded that the invention of claims 73 and 74 is a product made by the process of claim 67, wherein the process is open (*i.e.*, comprises the recited steps and any additional step). Furthermore, the claims are directed to an “infectious herpes virus genomic sequence” not a plasmid or BAC comprising the infectious herpes virus genomic sequence. Thus, the claim reads on any isolated or purified herpes virus genomic sequence that might be obtained by a process comprising the process of claim 67, such as a herpes virus genomic sequence obtained by process wherein the BAC vector is transfected into a cell and virions comprising the infectious herpes virus genomic sequence are obtained.

Applicant is further reminded that, because the claims are product-by-process, they read on the product made by any means. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”

As Applicant acknowledges, Messerle teaches the production of infectious herpes virus genomic sequences. Unless the process of producing the infectious herpes virus genomic sequences recited in claim 67 imparts an identifiable property that would not be present in the infectious herpes virus genomic sequences produced by the method of Messerle, the claimed invention is anticipated by the art. The fact that the starting material used in the process is different is immaterial because what is claimed is the product of the process. The claims are anticipated because the infectious herpes virus genomic sequence of Messerle could be produced

Art Unit: 1636

by the method of claim 67 given the process steps explicitly recited in the claim and sufficient additional process steps, which are also encompassed by the process of claim 67. In other words, because there is no demonstrable difference between an infectious herpes virus genomic sequence produced from a single plasmid and a herpes virus genomic sequence produced from two plasmids by homologous recombination, the claims are anticipated by the infectious herpes virus genomic sequence of Messerle.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 U.S.C. §102(b).

***Allowable Subject Matter***

Claims 36, 37 and 40-70 are allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1636

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Daniel M. Sullivan, Ph.D.  
Primary Examiner  
Art Unit 1636